MAR 1 2 2014

K131675

Section 8: Special 510(k) Summary

The following information is provided as required by 21 CFR § 807.92 for EPRT Technologies' 510(k) premarket notification. In response to the Safe Medical Devices Act of 1990, the following is a summary of the safety and effectiveness information upon which the substantial equivalence determination is based.

Sponsor: EPRT Technologies
1925 Angus Avenue, Unit D
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Contact: Katherine Blake
President
EPRT Technologies.
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Simi Valley, CA 93063 USA
(805) 526-2184

Date of Submission: June 4, 2013

Proprietary Name: EPRT Bodihealth TENS System with Silver Wrap

Common Name: Transcutaneous Electrical Nerve Stimulator for Pain Relief

Regulatory Class: Class II

Product Codes: GZJ

Regulation Number: 21CFR 882.5890

Predicate Device(s): EPRT Bodihealth System (K052836) with Foam and Rubber Wrap

Device Description:

The Bodihealth TENS system was previously described in K052836. The Silver Wrap is the component of the Bodihealth System that is used to transfer the energy from the Bodihealth device to the patient. It consists of a MediSponge foam 100 to which silver fabric is laminated, and then covered by urethane.

The silver wrap is one-piece and consists of (a) a Urethane outer layer, (b) an adhesive layer, (c) a silver plated nylon conductive layer and (d) a foam layer that acts as the material that contacts the patient.

The silver wrap functions as the means to conduct a maximum current of 3 milliamperes at 0.000732 Hz for 23 minutes. The electric currents produced are compatible with the natural electric currents of the human body.

Technological Characteristics:

The BodiHealth device is used to generate pulses which may be varied in frequency and pulse duration by potentiometer type controls. The pulses are amplified and coupled to output jacks to which the wrap is attached by wires.

Intended Use:

The EPRT Bodihealth TENS System (Transcutaneous Electrical Nerve Stimulator for Pain Relief) with Silver Wrap is intended for temporary symptomatic relief and management of chronic intractable pain and as an adjunctive treatment in the management of post-surgical and post-traumatic pain.

Comparison to Predicate Devices:

The EPRT Bodihealth TENS System with Silver Wrap has the same intended use and similar technological characteristics as the Bodihealth TENS System with previous with the Foam and Rubber Wrap described in K052836. Bench testing has proven the Silver Wrap to be equivalent to the Foam and Rubber Wrap previously used.

Design Control Summary

Design Input	Design Output	Verification/Validation
Obtain foam component equivalent to that used in predicate wrap	Medi-Sponge 100 selected as a suitable replacement	Engineering Testing meets the requirements as shown in this section.
Simplify the device from a two-piece system to a single-piece wrap	Successful development of a one-piece wrap	Improved and simplified as described in User Preference Testing shown in this section.
Reduce the resistance encountered in the previous rubber Strap/Conco foam.	One-piece silver wrap reduced the resistance as required in design input	Engineering testing demonstrated that the silver wrap has over 1/24th the resistance as the predicate (see User Preference Testing shown in this section)
Improve uniform energy transfer from the Bodihealth device to the patient.	Silver fabric is silver plated over nylon that is then laminated to foam with a hot melt grid adhesive. The grid pattern allows a conductive path from the silver fabric through the wet foam.	See Engineering Testing meets the requirements as shown in this section
Ensure that wave form and energy output of the improved device matches that of the predicate	Equivalent to predicate	See Engineering Testing shown in this section demonstrates equivalent waveforms to the predicate

Conclusion:

The EPRT Bodihealth TENS System with Silver Wrap has a similar design and the same intended use as the predicate wrap used in EPRT Bodihealth System (K052836). Biocompatibility testing and the current knowledge of the material provided by scientific literature demonstrated the appropriateness of the device materials for the proposed intended use. Engineering testing confirms that there is no change in the energy delivered to the patient due to the modification of the wrap component.

The test data demonstrate that the EPRT Bodihealth TENS System with Silver Wrap is substantially equivalent to the predicate (previous) wrap used in the device and that there is no change in the safety and effectiveness due to the modification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

March 12, 2013

EPRT Technologies, Inc.
c/o Jeff Morgan
JWM Associates LLC
15-2807 Puna Parkway
Pahoa, HI 96778

Re: K131675
Trade/Device Name: EPRT Bodihealth TENS System with Silver Wrap
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator for Pain Relief
Regulatory Class: Class II
Product Code: GZJ
Dated: February 6, 2014
Received: February 11, 2014

Dear Mr. Morgan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Carlos L. Pena -S

Carlos L. Peña, PhD, MS
Director
Division of Neurological and
Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K131675

Device Name
EPRT Bodihealth TENS System with Silver Wrap

Indications for Use *(Describe)*
The EPRT Bodihealth TENS System (Transcutaneous Electrical Nerve Stimulator for Pain Relief) with Silver Wrap is intended for temporary symptomatic relief and management of chronic intractable pain and as an adjunctive treatment in the management of post-surgical and post-traumatic pain.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Carlos L. Pena -S

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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